K020159 page 1 of 2

510(k) Summary

Smith & Nephew TwinFix Ti Quick T

MAR 2 6 2002

Date Prepared:

January 7, 2002

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

A. Submitter

Smith & Nephew, Inc.
Endoscopy Division
160 Dascomb Road
Andover, MA 01810

B. Company Contact

William McCallum
Regulatory Affairs Specialist

C. Device Name

Trade Name:	Smith & Nephew TwinFix Ti Quick T
Common Name:	Suture Anchor Suture, Nonabsorbable, Polyester
Classification Name:	Screw, Fixation, Bone

D. Predicate Devices

Acufex T-Fix Rotator Cuff Guide System, K941364
PEBA Anchor/Suture Combination K972326

E. Description of Device

The Smith & Nephew TwinFix Ti Quick T is a sterile single use anchor system which is designed to anchor suture to bone for the reattachment of soft tissues.

F. Indications For Use

The Smith & Nephew TwinFix Ti Quick T is indicated for use as a suture anchor to facilitate percutaneous or endoscopic soft tissue procedures. The Smith & Nephew Suture Anchor is indicated for shoulder, foot, ankle, elbow, knee, wrist and hand. Examples of such procedures include:
Shoulder:
Bankart lesion repairs, SLAP lesion repairs, acromio-clavicular separation repairs, rotator cuff repairs, capsular shift or capsulolabral reconstructions, biceps tendonesis, and deltoid repairs.
Foot and Ankle:
Hallux Valgus repairs, medial or lateral instability repairs/reconstructions, achilles tendon repairs/reconstructions, midfoot reconstructions, and metatarsal ligament/tendon repairs/reconstructions.
Elbow, Wrist and Hand:
Scapholunate ligament reconstructions, ulner or radial collateral ligament reconstructions, tennis elbow repair, and biceps tendon reattachment.
Knee:
Extra-capsular repairs: medial collateral ligament, lateral collateral ligament, and posterior oblique ligament. Iliotibial band tendonesis, and patellar realignment and tendon repairs, including vastus medialis obliquous advancement.

G. Comparison of Technological Characteristics

The Smith & Nephew TwinFix Ti Quick T is substantially equivalent in design, function, and intended use to the following predicate devices:

Acufex T-Fix Rotator Cuff Guide System, K941364 (May 16, 1994). T-Bar

PEBA Anchor/Suture Combination, K972326 (June 23, 1997). Anchor and Suture

William McCallum
Regulatory Affairs Specialist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 6 2002

Mr. William McCallum
Regulatory Affairs Specialist
Smith & Nephew, Inc
Endoscopy Division
160 Dascomb Road
Andover, Massachusetts 01810

Re: K020159
Trade/Device Name: Smith & Nephew TwinFix Ti quick T
Regulation Number: 888.3040
Regulation Name: Screw, Fixation, Bone
Regulatory Class: II
Product Code: HWC
Dated: January 16, 2002
Received: January 17, 2002

Dear Mr. McCallum:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number : K020159

Device Name: Smith & Nephew TwinFix Ti Quick T

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(PLEASE DO WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Yes OR Over-the-Counter No
(Per 21 CFR 801.109)
(Optional Format 1-2-96)

for Mark N Milhern
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K020159